IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MANCHANDA, Rajesh — Examiner: San Ming R. Hui

Serial No.: 09/855,542 — Group Art Unit: 1617

Filed: May 16, 2001 — Confirmation No.: 9728

Title: STABILIZATION OF RADIONUCLIDE-CONTAINING COMPOSITIONS

REPLY BRIEF UNDER 37 C.F.R. §41.41

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This Reply Brief is submitted under 37 C.F.R. §41.41 in response to the Examiner's Answer, mailed March 9, 2007. Appellants maintain full reliance upon their Brief filed November 14, 2006. The following points are made for emphasis or clarification of points made in the Brief in light of the comments thereon in the Examiner's Answer and/or are made in response to new points of argument raised in the Examiner's Answer.

1. The Examiner's Answer on page 3, last paragraph, and page 4, last paragraph, points to Solanki at col. 7, line 31, to col. 8, line 50, as providing a teaching of using sodium iodide or potassium iodide to stabilize radiopharmaceutical complex compositions by addition to a Tc-99m HMPAO complex. This is an incorrect reading of Solanki. Solanki does not teach or suggest at col. 7, line 31, to col. 8, line 50, adding sodium or potassium iodide to the Tc-99m HMPAO complex. This portion of Solanki relates to preparing the eluate and teaches "sodium iodide was added to the fresh eluate." See particularly col. 7, lines 55-57. The eluate is the Tc-99m pertechnetate eluate solution, not the HMPAO complex; see, particularly col. 7, lines 31-35. The eluate is the radionuclide before it is combined with the complexing/targeting agent. Solanki does not teach or suggest the addition of sodium iodide or any other iodide salt to the HMPAO complex as a stabilizer for the complex.
2. In the first paragraph of page 5 of the Examiner's Answer it is stated "it is generally known to use a weak oxidizing agent such as iodide to improve stability of

radiopharmaceutical agents." Appellants respectfully submit that there is no reference or other evidentiary basis on the record to support this statement. The general use of iodide as a stabilizing agent is not taught by either of the cited Solanki or Cyr references and no other basis for such allegation has been provided on the record.

3. Appellants respectfully submit that the Examiner's Answer at page 5, first paragraph (or elsewhere) fails to provide any substantive rebuttal of the argument in the Brief (paragraph bridging pages 4-5) that Solanki and Cyr are directed to stabilizing different types of radiopharmaceuticals using different types of agents for doing so. As shown in point 2 above, the statement regarding the general knowledge in the art is not supported on the record. The Examiner's Answer otherwise provides a conclusory statement that there is a reasonable expectation of success but fails to address why there would be such reasonable expectation when the references are directed to stabilizing different types of compositions using functionally distinct (see below) types of agents.
4. Appellants believe that the Examiner's Answer at page 5, second paragraph, misstates the appellants' position regarding the distinction of the weak oxidizing agents used in Solanki and the antioxidant agents used in Cyr. The argument in the Brief (e.g., paragraph bridging pages 4-5) was that Solanki teaches an oxidizing agent for stabilization of their types of radiopharmaceuticals whereas Cyr teachings an antioxidant for stabilizing different peptide-based radiopharmaceuticals. Thus, because the stabilizing agents are functionally opposite and were taught for stabilizing different types of radiopharmaceuticals, there is no reasonable expectation that the agents would be interchangeably useful to stabilize the different types of radiopharmaceuticals.
5. In connection with point 4 above, the Examiner's Answer also cites col. 3, lines 5-6, of Solanki which relates to the use of antioxidants, such as ascorbic acid, in previous radiopharmaceuticals. Such teaching fails to suggest the use of antioxidants in Solanki's own radiopharmaceutical complexes and, thus, fails to support the argument made in the Examiner's Answer. The statement in the Examiner's Answer that "ascorbic acid does not change the rate of degradation" refers to Solanki at col. 6, lines 1-3. Read in context, this statement strongly supports rather than contradicts

appellants' position. Solanki teaches that their complex has stability problems and that ascorbic acid failed to change the rate of the degradation problem (i.e., it did not work). Further, Solanki states that ascorbic acid is detrimental because "in fact it appears to prevent the formation of the Tc-99m HMPAO complex." This strongly supports appellants position that one of ordinary skill in the art would not expect from the cited references that agents useful for stabilizing Solanki's radiopharmaceuticals would also be useful for stabilizing Cyr's radiopharmaceuticals.

6. In further connection with point 4 above, the Examiner's Answer (sentence bridging pages 5-6) alleges that "it was known that potassium iodide can stabilize the radiopharmaceuticals because it can minimize the excess stannous ion," citing col. 5, lines 5-12, of Solanki. Solanki does suggest the possibility that stability of its complex can be improved by minimizing excess stannous ions. However, there is no support for the allegation that potassium iodide provides such a function. There is no mention of potassium iodide or its effects at all in this part of the Solanki disclosure.

For the above reasons and the reasons set forth in Appellants' Brief, it is submitted that the Final Rejection of claims 1-4, 6, 8-10 and 32-33, on appeal, is in error and should be reversed.

Respectfully submitted,

/John A. Sopp/
John A. Sopp, Reg. No. 33,103
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: DITI-0136

Date: May 9, 2007

JAS/cak